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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,840	10/30/2003	David W. Wynn	MCP-5021	9284

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EXAMINER	
GEORGE, KONATA M	
ART.UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/697,840	WYNN ET AL.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22 are pending in this application.

Action Summary

1. The rejection of claims 9 and 10 under 35 U.S.C. 112, second paragraph as being indefinite is hereby withdrawn.

2. The rejection of claims 1-22 under 35 U.S.C. 103(a) over Ratnaraj et al. in view of Singh et al. and Barry et al. is being maintained for the reasons stated in the previous office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratnaraj et al. (US 5,658,919).

Applicants claim a liquid suspension of particles of NSAID and/or acetaminophen wherein the particles are covered with one layer of a controlled release composition.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Ratnaraj et al. discloses a novel suspension system containing acetaminophen (col. 2, lines 46-55). Column 4, lines 1-2 teach the system is suitable from suspending acetaminophen powder. The suspending system (examiner relates it to the vehicle as claimed by applicant) comprises xanthan gum and a mixture of microcrystalline cellulose and sodium carboxymethylcellulose (col. 2, lines 51-53). Table 1 of columns 6 and 7 disclose the addition of water to the vehicle, a glycol such as propylene glycol, sweeteners and flavoring agents.

Singh et al. discloses a pharmaceutical suspension system comprising finely divided pharmaceutically active compounds and liquid excipient suspension system comprising water, and the suspending agents xanthan gum and hydroxypropyl methylcellulose (col. 1, lines 4-12). Column 2, lines 30-35 teach that the active compounds can be non-steroidal anti-inflammatory drugs (NSAIDs) and other analgesic drugs such as acetaminophen. Of the NSAIDs for use in the system propionic acid derivatives can be employed (col. 3, lines 3-7). Preservatives, sweeteners, and flavoring agents can be used in the system (col. 4, lines 5-10). The various examples in

columns 4-7 teach the concentrations of the drug as about 3.20% and a least 40% water.

Barry et al. discloses sustained release formulations of pharmaceutically active substances. The formulations comprise a core and a coating. Examples of the active agents can be non-steroidal anti-inflammatory drugs (NSAIDs) (col. 7, lines 3-27). Column 5, lines 64-65 teach that the formulation for the granules provides a sustained release over a period of 12 hours. Column 6, line 49 through column 7, line 2 teaches examples of the coating such as acrylic polymers sold under the name Eudragit™.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

The prior art does not teach the particles being coated with a controlled release composition, the composition having a therapeutic effect of least about 8 hours and the NSAID is a propionic acid derivative.

Finding of prima facie obviousness

***Rational and Motivation* (MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combine teachings of Ratnaraj et al. (a suspension of acetaminophen) in view of Singh et al. (a suspension of NSAIDs) and of Barry et al. to disclose the claimed invention. One of ordinary skill would use the coating compositions of Barry et al. to coat the drugs of Ratnaraj et al. or Singh et al. for the

purpose of providing a sustained release profile for the active agent. With respect to the claimed concentrations, absent a clear showing of criticality, the determination of particular concentrations is within the skill of the ordinary worker as part of the process of normal optimization to achieve the desired results of the claimed composition.

Response to Arguments

4. Applicant's arguments filed October 16, 2006 have been fully considered but they are not persuasive.

Applicants argue that Barry is directed towards a granular sustained release formulation presented in the form of effervescent or water-dispersible tablets. Barry is being relied upon to teach coating the active substance with a coating that provides a sustained release profile of over a period of 12 hours (col. 5, lines 64-65).

The combination of these references would result in the claimed invention. One of ordinary skill in the art would coat the acetaminophen or NSAID for several reasons 1) to mask the bitter taste of the drug and 2) to provide a sustained release of the drug over a period of time for the purposes of providing relief of pain or of anti-inflammatory relief. The coatings of Barry could be relied upon as it teaches a sustained release coating (over a period of 12 hours). Singh teaches examples of NSAIDs that could be used. Thus the combination of the references teaches the claimed invention.

Conclusion

5. Claims 1-22 remain rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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